BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New Rules I through XIV pertaining to the State Trauma Care System	)))	NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION

TO: All Interested Persons

1. On April 12, 2006, at 1:30 p.m., a public hearing will be held in the auditorium of the Department of Public Health and Human Services Building, 111 N. Sanders, Helena, Montana to consider the proposed adoption of the above-stated rules.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice or provide reasonable accommodations at the public hearing site. If you need to request an accommodation, contact the department no later than 5:00 p.m. on April 3, 2006 to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970; e-mail dphhslegal@mt.gov.

2. The rules as proposed to be adopted provide as follows:

RULE I DEFINITIONS In addition to the definitions in 50-6-401, MCA, the following definitions apply to this subchapter:

(1) "Appendix I of the State Trauma Plan" means the appendix of the 2006-2010 Montana Trauma System Plan that contains the requirements for a facility to meet in order to be designated as a particular type of trauma care facility. The department adopts and incorporates by reference Appendix I of the department's 2006-2010 Montana Trauma System Plan, which sets forth the facility requirements for designation of trauma facilities. A copy of Appendix I of the 2006-2010 Montana State Trauma Plan may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Emergency Medical Services and Trauma Systems Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(2) "Appendix J of the State Trauma Plan" means the appendix of the 2006-2010 Montana Trauma System Plan that contains the criteria for including a patient in the state trauma register, the format specified by the department for a health care facility trauma registry, and the requirements for collection of state trauma register and health care facility registry data. The department adopts and incorporates by reference Appendix J of the department's 2006-2010 Montana Trauma System Plan. A copy of Appendix J of the 2006-2010 Montana Trauma System Plan may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Emergency Medical Services and Trauma Systems Section,

1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(3) "Application" means the submission of written information by a health care facility, on forms required by the department, requesting designation as a specific level of trauma facility and providing information regarding its compliance with the criteria in Appendix I of the State Trauma Plan concerning the resources a facility must have to qualify as that level of trauma facility.

(4) "Area trauma hospital" means a health care facility that is designated by the department as having met the essential standards for area trauma hospitals as specified in Appendix I of the State Trauma Plan.

(5) "Community trauma facility" means a health care facility that is designated by the department as having met the standards for a community trauma facility as described in Appendix I of the State Trauma Plan.

(6) "Corrective action plan" means the specific actions that are required of a health care facility by the department in order to be in compliance with trauma facility requirements and that are included in a plan written by the health care facility and approved by the site review team.

(7) "Designated facility" refers to a health care facility that has been determined by the department to satisfy the requirements of one of the four categories of trauma facilities as described in Appendix I of the State Trauma Plan.

(8) "Designation" means a formal determination by the department that a health care facility has met the requirements for a level of trauma facility as described in Appendix I of the State Trauma Plan.

(9) "Designation subcommittee" means members of the State Trauma Care Committee's Performance Improvement Subcommittee that are selected by the Trauma Care Committee's chairperson to evaluate a site review team's report and who make recommendations to the department concerning a health care facility's designation.

(10) "Emergency department" means an area of a licensed health care facility that customarily receives patients in need of emergency evaluation or care.

(11) "Focused review" means a method established by the department to assess a health care facility's compliance with a corrective action plan to meet the resource criteria in Appendix I of the State Trauma Plan.

(12) "Nurse practitioner" means a person who is licensed as a professional registered nurse and approved by the Montana Board of Nursing as a nurse practitioner.

(13) "Peer review" means the confidential review by health care practitioners from multiple disciplines of provider performance in order to reduce morbidity and mortality and to improve the care of patients.

(14) "Physician" means a person licensed to practice medicine in Montana by the Montana Board of Medical Examiners.

(15) "Physician's assistant" means a person who is licensed to practice as a physician assistant by the Montana Board of Medical Examiners.

(16) "Practitioner" means a physician, nurse practitioner, or physician's assistant.

(17) "Provisional designation" means that a health care facility has substantially, although not completely, complied with the requirements for a given level of trauma facility, that a corrective action plan has been submitted by the facility

to the department, and that the facility has been authorized by the department to serve as a trauma facility on a temporary basis.

(18) "Regional trauma center" means a health care facility that is designated by the department as having met the criteria for a regional trauma center as described in Appendix I of the State Trauma Plan.

(19) "Regional Trauma Care Advisory Committee" means a regional committee composed of representatives from each of the region's trauma facilities established pursuant to 50-6-411, MCA.

(20) "Site review team" means a group of individuals selected by the department who have expertise in trauma care and trauma program administration and that evaluates a medical facility's compliance with required trauma facility criteria.

(21) "Site survey" means the process by which the site review team visits a health care facility that has applied for trauma facility designation, reviews the compliance of the medical facility with the applicable trauma facility criteria, and makes recommendations regarding designation to the department.

(22) "Trauma diversion" means a health care facility that temporarily does not have all the resources available to optimally resuscitate a seriously injured patient, with the result that such a patient is diverted from that hospital prior to arrival there and arrangements are made simultaneously for the patient to be received and treated at another facility that can provide more readily available and appropriate medical care.

(23) "Trauma patient" means an individual suffering from a trauma as defined in 50-6-401, MCA.

(24) "Trauma receiving facility" means a health care facility that is designated by the department as having met the criteria for a trauma receiving facility as described in Appendix I of the State Trauma Plan.

AUTH: 50-6-402, MCA
IMP: 50-6-401, 50-6-402, MCA

RULE II TRAUMA REGIONS (1) The following regions are designated as trauma regions:

(a) the western trauma region, consisting of Beaverhead, Deer Lodge, Flathead, Granite, Lake, Lincoln, Mineral, Missoula, Powell, Ravalli, Sanders, and Silver Bow counties;

(b) the central trauma region, consisting of Blaine, Broadwater, Cascade, Chouteau, Glacier, Hill, Jefferson, Judith Basin, Lewis and Clark, Liberty, Meagher, Pondera, Teton, and Toole counties; and

(c) the eastern trauma region, consisting of Big Horn, Carbon, Carter, Custer, Daniels, Dawson, Fallon, Fergus, Gallatin, Garfield, Golden Valley, Madison, McCone, Musselshell, Park, Petroleum, Phillips, Powder River, Prairie, Richland, Roosevelt, Rosebud, Sheridan, Stillwater, Sweet Grass, Treasure, Valley, Wheatland, Wibaux, and Yellowstone counties.

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

RULE III REGIONAL TRAUMA CARE ADVISORY COMMITTEES (1) In addition to the requirements specified in 50-6-412, MCA, each Regional Trauma Care Advisory Committee must do the following:

(a) meet quarterly to identify specific regional trauma needs and to define corrective strategies;

(b) propose trauma care guidelines or protocol, backed by evidence and research showing their efficacy, to the State Trauma Care Committee;

(c) develop a Regional Trauma Plan that addresses each of the following trauma system components:

(i) prehospital trauma communications and dispatch;

(ii) medical control and treatment protocols for prehospital caregivers;

(iii) triage and transportation of trauma victims;

(iv) facility resources in the region for trauma patients;

(v) interfacility transfer of trauma patients;

(vi) rehabilitation resources;

(vii) criteria to determine what the composition of a patient's trauma team should be given the nature of the patient's trauma;

(viii) trauma performance improvement; and

(ix) disaster management; and

(d) keep minutes of each Regional Trauma Care Advisory Committee meeting and submit a copy to the State Trauma Care Committee.

(2) Each Regional Trauma Care Committee must have, as a minimum, a subcommittee structure that addresses each of the following elements:

(a) trauma performance improvement;

(b) the Regional Trauma Plan;

(c) trauma education;

(d) prehospital trauma issues; and

(e) injury prevention and control.

(3) In accordance with 50-6-415, MCA, Regional Trauma Care Advisory Committee and subcommittee meetings must be open to the public, and the information presented at such meetings is public as well, unless the committee or subcommittee determines that the meeting, or a portion thereof, will perform peer review and performance improvement activities, in which case:

(a) the meeting, or the relevant portion thereof, is limited to:

(i) members of the committee or subcommittee; and

(ii) guests who further the process of performance improvement, are invited by the performance improvement subcommittee chairperson, and are approved by the Regional Trauma Care Advisory Committee chairperson in advance;

(b) each committee or subcommittee member and guest must sign a form indicating they will not divulge any proceedings of the closed meeting, conversations during the meeting, or documents used during the meeting; and

(c) the minutes and the information presented, including all records and deliberations of the meeting, are confidential and not discoverable.

(4) If a meeting is closed pursuant to (3), the Regional Trauma Care Advisory Committee may still develop summary reports, findings, and recommendations to the State Trauma Care Committee, Regional Trauma Care Advisory Committee, an

Individual Trauma Facility Trauma Program, or an individual health care practitioner.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-412, 50-6-415, MCA

RULE IV STATE TRAUMA CARE COMMITTEE (1) The State Trauma Care Committee shall:

(a) meet quarterly to identify specific statewide trauma needs and to define corrective strategies;

(b) keep minutes and provide copies of those minutes to each Regional Trauma Care Advisory Committee;

(c) advise the department in the preparation of the annual trauma system report;

(d) assist in the development and oversight of the State Trauma System Plan; and

(e) approve the state trauma system plan.

(2) The Trauma Care Committee must, at a minimum, have a subcommittee structure that addresses each of the following:

(a) trauma performance improvement;

(b) organization and emergency preparedness;

(c) trauma education;

(d) injury prevention and control;

(e) public advocacy and legislation; and

(f) designation of trauma facilities.

(3) The subcommittee of the State Trauma Care Committee responsible for designation of trauma facilities must review the site survey report and make a recommendation to the department regarding actions to be taken on the trauma designation application of a potential trauma facility.

(4) In accordance with 50-6-415, MCA, state trauma care committee and subcommittee meetings are open to the public and the information presented is considered public information unless the committee or subcommittee determines that the meeting, or a portion thereof, will perform peer review and performance improvement activities, in which case:

(a) the meeting, or the relevant portion thereof, is limited to:

(i) members of the committee or subcommittee; and

(ii) guests who further the process of performance improvement, are invited by the Performance Improvement Subcommittee chairperson, and are approved by the Trauma Care Committee chairperson in advance;

(b) each committee or subcommittee member and guest must sign a form indicating they will not divulge any proceedings of the meeting, conversations during the meeting, or documents used during the meeting; and

(c) the minutes and the information presented, including all records and deliberations of the meeting pertaining to the peer review and performance improvement activities, are confidential and not discoverable.

(5) If a meeting is closed pursuant to (4), the committee or subcommittee may still develop summary reports, findings, and recommendations to the State Trauma Care Committee, Regional Trauma Care Advisory Committee, an individual

Trauma Facility Trauma Program, or an individual health care practitioner.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-415, MCA

RULE V LEVELS OF TRAUMA FACILITIES (1) The department may designate a health care facility as belonging to one of the following four levels of trauma facilities:

(a) regional trauma center;
(b) area trauma hospital;
(c) community trauma facility; or
(d) trauma receiving facility.

(2) Requirements for each level are contained in Appendix I of the State Trauma Plan.

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

RULE VI COMPOSITION OF SITE REVIEW TEAMS (1) The site review team for regional trauma centers must be composed of out-of-state surveyors, including a general surgeon and a trauma nurse coordinator, as well as department staff and any other members determined to be necessary by the department or requested by the health care facility being reviewed.

(2) The site review team for area trauma hospitals and community trauma facilities must be composed of either out-of-state or in-state surveyors from a Montana trauma region other than the one in which the facility is located and must include a general surgeon, a trauma nurse coordinator, department staff, and other members determined to be necessary by the department or requested by the health care facility being reviewed.

(3) The site review team for a trauma receiving facility must be composed of either out-of-state or in-state surveyors and must include a physician, a trauma nurse coordinator, department staff, and other members determined to be necessary by the department or requested by the health care facility being reviewed.

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

RULE VII DESIGNATION PROCEDURES FOR FACILITIES NOT VERIFIED BY AMERICAN COLLEGE OF SURGEONS (1) A Montana health care facility that is not currently verified by the American College of Surgeons as meeting the American College of Surgeons' criteria to qualify for verification as a trauma facility and that wishes a designation or renewal of designation as a Montana trauma facility shall submit to the department an application for trauma facility designation, supplied by the department.

(2) The application must:

(a) specify the level of designation for which the facility is applying; and
(b) provide information about the facility's compliance with the trauma facility

resource criteria in Appendix I of the State Trauma Plan that are required for that level of trauma facility.

(3) The department shall review the application for completeness and shall within 30 days after receiving the application notify the health care facility that:

(a) the application is complete; or

(b) the application is incomplete and request additional information.

(4) When the application is complete, the department shall:

(a) select a site review team; and

(b) with a minimum of 60 days advance notice, notify the facility of the scheduled dates for the site survey and of the site review team members.

(5) The health care facility shall:

(a) notify the department in writing within 10 working days if it objects to one or more members of the site review team due to a perceived conflict of interest, and provide documentation of clear and convincing evidence for its concern including, but not limited to, the member's past or potential financial or personal gain, past or potential employment, or gain from the use of confidential information; and

(b) prohibit its administration, faculty, medical staff, employees, and representatives from having any contact with site review members prior to the site survey, except as directed by the department.

(6) The site review team shall:

(a) review the commitment and capabilities of the applicant health care facility to meet the resource criteria described in Appendix I of the State Trauma Plan for the level of designation sought, based upon consideration of all pertinent information, including but not limited to:

(i) review of the application for designation;

(ii) inspection of the facility and required equipment;

(iii) interview with appropriate individuals;

(iv) review of medical records;

(v) review of inpatient logs and hospital emergency department logs;

(vi) review of hospital trauma registry entries and reports;

(vii) review of documentation of trauma performance improvement;

(viii) review of call rosters, staffing schedules, and meeting minutes;

(ix) review of injury prevention and education programs; and

(x) other documentation as necessary to assess the facility's compliance with these rules;

(b) make a verbal report of its findings through an exit interview to the applicant upon completion of the site survey and prior to leaving the facility; and

(c) make a written report of its findings and recommendations to the department within 30 days following the on-site survey of the facility.

(7) The department shall review the report of the site review team and forward a copy to the designation subcommittee.

(8) The designation subcommittee shall review the report of a site review team at the next quarterly State Trauma Care Committee meeting and make a recommendation to the department regarding the trauma designation of the applicant facility.

(9) The department shall:

(a) determine the final designation of the facility based on consideration of

the application, the recommendations of the site review team, and the recommendations of the designation subcommittee; and

(b) notify the applicant of its decision in writing within 30 days after receiving the recommendation from the designation subcommittee.

(10) The department shall take one of the following actions:

(a) designate the applicant as qualifying for the trauma facility level requested, providing there is compliance with the trauma facility resource criteria in Appendix I of the State Trauma Plan;

(b) issue a provisional designation to the applicant provided:

(i) there are deficiencies noted but the facility is substantially compliant with the resource criteria and any deficiencies will not have an immediate detrimental impact on trauma patient care; and

(ii) the applicant has submitted to the site review team a corrective action plan, acceptable to the team, for the correction of the identified deficiencies;

(c) designate the applicant as a trauma facility at a different level from that for which the applicant applied, provided that:

(i) the applicant meets all of the requirements of the alternative trauma facility designation level; and

(ii) the applicant agrees to be designated at the alternative trauma facility designation level; or

(d) deny any trauma facility designation if:

(i) there is substantial noncompliance with the requirements; or

(ii) the deficiencies are fundamental or may have an immediate detrimental impact on trauma patient care.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-410, MCA

RULE VIII DESIGNATION PROCEDURES FOR FACILITIES VERIFIED AS A TRAUMA FACILITY BY AMERICAN COLLEGE OF SURGEONS (1) A health care facility with a current certificate of verification from the American College of Surgeons as a trauma facility qualifies as one of the following types of Montana trauma facility as set out in (2), providing it submits an application, department staff attend the on-site review conducted by the American College of Surgeons, and the facility demonstrates compliance with any requirements described in Appendix I of the State Trauma Plan that may exceed the American College of Surgeons' standards in the college's document entitled "Resources for Optimal Care of the Injured Patient: 1999". A copy of this document may be obtained as set forth in (8).

(2) A current certificate of verification for the following levels established by the American College of Surgeons qualified a health care facility as the following type of Montana trauma facility:

(a) a level II trauma center qualifies as a regional trauma center;

(b) a level III trauma center qualifies as an area trauma facility; and

(c) a level IV trauma center qualifies as a community trauma facility.

(3) A Montana health care facility that is seeking verification or reverification by the American College of Surgeons as a trauma center and wishes to be designated as a Montana trauma facility must submit to the department:

(a) an application for designation, on a form approved by the department, that:

(i) specifies the level of designation for which the facility is applying; and

(ii) includes a copy of the American College of Surgeons' prereview questionnaire;

(b) any additional information required by the department to verify compliance with any requirements described in Appendix I of the State Trauma Plan that exceed the American College of Surgeons' standards;

(c) notification of the scheduled dates of the American College of Surgeons' site survey to allow for department participation in the site review; and

(d) upon receipt, a copy of the American College of Surgeons' letter indicating if the facility was successfully verified as a trauma facility.

(4) The department shall review the application for completeness and shall within 30 days after receiving the application:

(a) notify the facility that the application is complete; or

(b) notify the facility that the application is incomplete and request additional information.

(5) When the application and the site review are complete, and the American College of Surgeons' letter is received that indicates whether the facility is successfully verified as a trauma facility, the department shall provide a copy of the application and the letter to the designation subcommittee at the next quarterly State Trauma Care Committee meeting.

(6) The designation subcommittee shall review the application and American College of Surgeons' letter at the next quarterly State Trauma Care Committee meeting and make a recommendation to the department regarding the trauma designation of the applicant facility.

(7) Within 30 days after receiving a recommendation from the designation subcommittee, the department shall take one of the following actions:

(a) designate the applicant at the trauma facility level requested providing there is compliance with these rules;

(b) issue a provisional designation to the applicant provided:

(i) there are deficiencies noted but the facility is substantially compliant with the resource criteria and the deficiencies will not have an immediate detrimental impact on trauma patient care; and

(ii) the applicant has submitted to the department a corrective action plan, acceptable to the department, for the correction of the deficiencies;

(c) designate the applicant as a trauma facility at a different level from that for which the applicant applied, provided that:

(i) the applicant meets all of the requirements of the alternative trauma facility designation level; and

(ii) the applicant agrees to be designated at the alternative trauma facility designation level; or

(d) deny any designation if there is substantial noncompliance with the requirement, or the deficiencies may be a threat to public health and safety.

(8) The department adopts and incorporates by reference "Resources for Optimal Care of the Injured Patient: 1999", published by the American College of Surgeons. The document contains the trauma facility criteria used by the American

College of Surgeons in its process for verification of trauma facilities. A copy may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Emergency Medical Services and Trauma Systems Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-410, MCA

RULE IX LENGTH OF DESIGNATION (1) When a trauma facility is designated as such pursuant to [Rule VII], the period of designation is for three years beginning from the date the notice of designation is issued.

(2) When a trauma facility is designated as such pursuant to [Rule VIII], the expiration date of the designation shall coincide with the expiration date of the American College of Surgeons' Certificate of Verification. Upon expiration of the Certificate of Verification, the facility may be granted a Montana designation extension of up to six months if the department receives documentation that an American College of Surgeons' verification survey is anticipated.

(3) A provisional designation imposed pursuant to [Rule XI] is valid for a period determined by the department in consultation with the designation subcommittee, but not longer than 12 months. The provisional designation expires on the date set by the department unless the provisionally designated trauma facility:

(a) receives a focused review by the department in consultation with the designation subcommittee to determine if the corrective action plan has resulted in compliance with the required criteria; and

(b) the department determines that the corrective action plan has resulted in the facility successfully meeting the required criteria, in which case the department shall issue a designation as a trauma facility.

(4) A trauma facility may renew its designation by completing the requirements of [Rule VII] or [Rule VIII].

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

RULE X TRAUMA FACILITY REQUIREMENTS (1) A designated trauma facility must:

(a) adhere to these rules;

(b) continue to be a health care facility; and

(c) continue to provide the resources required for its designated level of trauma facility, as described in Appendix I of the State Trauma Plan.

(2) If the designated facility is unable to provide the care required by (1), it must:

(a) observe the trauma diversion plan required by Appendix I of the State Trauma Plan for its facility; and

(b) immediately notify the department if the facility becomes unable to provide trauma services commensurate with its designation level for a period of more than one week.

(3) A designated facility may, without cause, terminate its trauma designation

after giving 90 days written notice to the department, the State Trauma Care Committee, and the Regional Trauma Care Advisory Committee.

(4) If, following its voluntary termination of trauma designation, a health care facility wishes to be reinstated as a trauma facility, the facility must reapply for designation by completing the requirements of [Rule VII] or [Rule VIII], whichever is applicable.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-410, MCA

RULE XI COMPLAINT INVESTIGATION, REVOCATION, OR EMERGENCY SUSPENSION (1) The department may review, inspect, evaluate, and audit trauma patient medical records, inpatient logs, hospital emergency department logs, trauma performance improvement documentation, and any other documents relevant to trauma care by any trauma facility at any time to verify compliance with these rules.

(2) The confidentiality of such records will be maintained by the department in accordance with state and federal law.

(3) The department will investigate written complaints alleging violation of these rules in the following manner:

(a) The department will request and the designated facility shall provide information that the department determines necessary to the investigation of the complaint.

(b) The results of a department investigation will be reviewed with the designation subcommittee.

(4) Following the completion of the investigation and review, the department may:

(a) take no action;

(b) initiate an emergency suspension of the facility's trauma designation;

(c) require the designated facility to submit a corrective plan of action for any deficiencies that were noted;

(d) change the designation of a trauma facility to provisional; or

(e) revoke the designation of the designated facility.

(5) The department will suspend the designation of a designated trauma facility on an emergency basis if the violation of these rules creates a substantial threat to public health or if the designated facility ceases to be a health care facility. The designated facility may appeal the emergency suspension pursuant to 50-6-410, MCA, but the emergency suspension shall remain in effect until a final decision is made by the department.

(6) The department may revoke a trauma facility designation if the facility:

(a) fails to comply with these rules;

(b) no longer is a health care facility;

(c) makes a false statement of a material fact in the application for designation, in any record required by these rules, or in a matter under investigation;

(d) prevents, interferes with, or attempts to impede in any way, the work of a department representative in the lawful enforcement of these rules; or

(e) falsely advertises or in any way misrepresents the facility's ability to care for trauma patients based on its trauma designation status.

(7) If a designated facility notifies the department that it will be temporarily noncompliant with its trauma facility designation criteria for longer than one week, the department, after consultation with the designation subcommittee, may take one or more of the following actions:

(a) conduct a focused review;

(b) modify the facility's designation status to provisional and require that a plan of correction be submitted to the department outlining how the deficiency will be corrected;

(c) change its designation level to be consistent with the trauma facility level for which it has the required resources; or

(d) suspend the trauma facility's designation on an emergency basis.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-410, MCA

RULE XII DENIAL, MODIFICATION, SUSPENSION, OR REVOCATION OF DESIGNATION, AND APPEAL (1) If the department proposes to deny, modify, suspend, or revoke a facility's trauma designation, the department shall notify the health care facility of that fact by registered or certified mail at the last address shown in the department records.

(2) The notice shall state the alleged facts that warrant the action and that the facility has an opportunity to request a hearing before the department to contest the decision.

(3) If the facility wants to appeal the department's decision, it must request a hearing in writing within 30 calendar days after the date of receipt of the notice. The request must be in writing and submitted to the Department of Public Health and Human Services, Office of Fair Hearings, P.O. Box 202953, Helena, MT 59620-2953.

(4) If a hearing is requested, the hearing will be held in accordance with the informal hearing procedures described in 2-4-604, MCA, and ARM 37.5.117 and 37.5.311.

(5) If the facility does not request a hearing by the deadline cited in (3), after being sent the notice of opportunity for hearing, the facility will be deemed as to have waived the opportunity for a hearing, and the department's decision to deny, modify, or revoke a facility's trauma designation will be final.

(6) As provided in [Rule XI], suspension of a trauma designation on an emergency basis is effective immediately upon receipt by the trauma facility of the notice required by (1), and remains in effect unless the facility files an appeal with the department and the suspension is lifted after a hearing.

AUTH: 50-6-402, MCA
IMP: 2-4-604, 50-6-402, 50-6-410, MCA

RULE XIII REAPPLICATION FOR DESIGNATION (1) Six months after the denial of its request for designation, a health care facility may reapply for trauma facility designation pursuant to [Rule VII] or [Rule VIII].

(2) If a health care facility's trauma designation has been revoked, one year

after the revocation was final, the facility may petition the department, in writing, to be allowed to reapply to be designated a trauma facility once again. The department may deny the opportunity to reapply if, after investigation, the department determines that the reason for the revocation continues to exist. If the application is allowed, the hospital or facility must meet the requirements of [Rule VII] or [Rule VIII], whichever is relevant.

AUTH: 50-6-402, MCA
IMP: 50-6-402, 50-6-410, MCA

RULE XIV TRAUMA REGISTRIES AND DATA REPORTING (1) For the purpose of improving the quality of trauma care, all Montana health care facilities, as defined in 50-6-401, MCA, must participate in the state trauma register by collecting and reporting to the department the data listed in (4), on the schedule required by (2).

(2) Within 60 days after the end of each quarter, each health care facility that provides service or care to trauma patients within Montana must submit to the department the information required by (4) concerning any trauma patient that it serves during any month of the quarter and who meets the criteria for inclusion in the trauma register that are set forth in Appendix J of the State Trauma Plan.

(3) The data must be submitted to the department's trauma register in the same format as the state register uses, unless the department allows an alternate means of submission if use of the department's prescribed format would impose a severe hardship on the reporting facility. Regional trauma centers and area trauma hospitals must submit the data electronically, and community trauma facilities, trauma receiving facilities and all other health care facilities treating trauma patients must submit the data using a paper format.

(4) The following data fields must be reported to the department:

(a) patient information that includes:

(i) a unique trauma patient identifier;

(ii) date of birth;

(iii) age;

(iv) sex;

(v) race; and

(vi) address;

(b) injury information that includes:

(i) date, time, and location of injury;

(ii) trauma injury diagnostic codes;

(iii) injury cause;

(iv) protective devices used by the patient, if any;

(v) results of alcohol or drug testing, if any; and

(vi) trauma injury diagnoses;

(c) prehospital information that includes:

(i) prehospital transport agencies;

(ii) patient extrication time;

(iii) emergency medical service (EMS) dispatch date;

(iv) EMS notification time;

(v) time of arrival at scene;
(vi) departure time from scene;
(vii) time of arrival at the facility;
(viii) triage criteria, including physiologic and anatomic conditions, injury circumstances, and comorbid factors;
(ix) EMS activation of trauma team;
(x) vital and neurologic signs;
(xi) treatment and procedures provided; and
(xii) whether a prehospital report is included in the facility patient medical record;
(d) interfacility transfer information that includes:
(i) the names of the referring and receiving facilities;
(ii) trauma team activation;
(iii) patient arrival and discharge date and times from the referring facility;
(iv) vital and neurologic signs;
(v) date, time, and results of tests and procedures performed;
(vi) treatment at the referring facility;
(vii) payor source; and
(e) inpatient care information that includes:
(i) the name of the facility;
(ii) emergency department admission and discharge dates and times;
(iii) trauma team activation;
(iv) emergency department vital and neurologic signs;
(v) status of intubation and ventilation;
(vi) date, time, and results of tests and procedures performed;
(vii) post emergency department destination;
(viii) admitting service;
(ix) previous admission for the injury in question, if any;
(x) total days in the intensive care unit;
(xi) total days on ventilator;
(xii) date for rehabilitation consult;
(xiii) date nutrition addressed;
(xiv) substance counseling, if applicable;
(xv) use of blood products, if applicable;
(xvi) facility discharge date and time;
(xvii) discharge disposition;
(xviii) functional ability at discharge;
(ixx) payor source;
(xx) hospital charges and payments received;
(xxi) for all deaths, if an autopsy was performed; and
(xxii) for all deaths, whether there was any donation of tissue or organs.
(5) Failure of a designated trauma facility to timely and accurately report to the department all data required by these rules is grounds for revocation of designation status.

AUTH: 50-6-402, MCA
IMP: 50-6-401, 50-6-402, MCA

3. The Emergency Medical Services and Trauma Systems Section of the Department of Public Health and Human Services (the department) proposes these new rules to improve trauma care in Montana. Trauma is any severe, abrupt injury to the human body caused by mechanical, environmental, thermal, or other physical force. It is the leading cause of death for Montanans between the ages of 1 and 44. It is the fourth leading cause of death for all age groups nationally.

Although the national death rates from injury have fallen, in Montana the rates have risen steadily since 1995. Trauma caused only 8.6% of the Montana deaths in 2002, but accounted for 30.5% of the total years of potential life lost before the age of 75. American Indians make up 6% of Montana's population yet have an injury death rate three times that of the national average. American Indians are dying 10 to 13 years younger than their non-Indian counterparts in this state.

The overreaching goal of a trauma system is to achieve, maintain, and coordinate elements of care to provide the right care to the public in the right place at the right time. Trauma research supports the validity of the "golden hour", which is that limited yet imperative time from injury occurrence to definitive care. After this crucial time has expired, the body's organ systems, even those uninvolved in the initial injury, may suffer irreparable and potentially fatal damage.

Rural trauma care in Montana is complicated by geographic isolation, time between injury and discovery, distance to health care, and the availability of local health care resources. Due to the vast distances between them, all Montana health care facilities must be prepared to provide initial care to injured patients while simultaneously expediting the patients' transfer to definitive care. This level of preparation and organization has been proven nationally to reduce the number of preventable deaths and disabilities.

Efforts to adopt national uniform standards for effective trauma care have varied during the past 30 years. Despite numerous professional organizations supporting trauma care improvements, the American College of Surgeons (ACS) Committee on Trauma, established in 1922, has proven to be the leading authority in improving trauma care nationwide. ACS issued its first guidelines on trauma care in 1976.

ACS's most recent standards are found in its publication "Resources for the Optimal Care of the Injured Patient: 1999", which provides criteria for excellence in trauma care and ACS's classification of trauma centers based on the centers' resource availability. ACS also developed a consultation/verification process whereby a hospital could be evaluated to determine if the ACS criteria are being met. The assessment involves a comprehensive on-site review conducted over a three day period by a multi-disciplinary team of national trauma experts.

In November 1990, the federal Trauma Care Systems Development Act (Public Law 101-590) was enacted providing funding and a legislative framework to encourage the development of trauma systems across the nation. Part of the act called for the

development of a model plan for trauma systems. In 1992, the Health Resources and Services Administration (HPSA) under the U.S. Department of Health and Human Services developed the Model Trauma Care System Plan for states to adopt.

In Montana, federal grant support from HPSA led to the formation of a state task force comprised of representatives from the prehospital, nursing and physician professions, hospital administration, Indian Health Services, and state legislators. The task force met between 1990 and 1994 and formulated the state's first trauma system plan. In 1989, the department, with input from the task force, implemented a statewide trauma register for hospitals.

The task force evolved into the State Trauma Care Committee (STCC), which currently exists. The committee meets on a quarterly basis and serves in an advisory role on medical and administrative issues regarding trauma care. The STCC also divided the state into three trauma regions based on patient referral patterns. The three Regional Trauma Advisory Committees (RTACs) represent each trauma region and meet quarterly.

In 1999, ACS performed its first consultation in Montana of the state's overall trauma care system. Many of the recommendations from ACS's assessment have been used to develop Montana's trauma system plan. Also, Montana's regional trauma centers in each of the three trauma regions have successfully obtained verification from ACS as level II trauma centers.

Currently, the STCC has devised and adopted the "2006-2010 Montana Trauma System Plan". The plan is the outcome of the years of trauma system development activities, including input from the system's trauma care providers and patients, the ACS trauma system evaluation of Montana, the results of over five studies on inappropriate care and preventable mortality, and data from the statewide trauma registry. Input and approval was also obtained from the three RTACs. The "2006-2010 Montana Trauma System Plan" is a voluntary system designed to provide an organized, preplanned response for the state's trauma patients by assuring optimal patient care and the most efficient use of limited health care resources.

In the midst of the state's activities to improve trauma care, the 1995 state legislature enacted the statutes found in Title 50, chapter 6, part 4, MCA, codifying the activities of the department, the STCC, and the RTACs. The statutes provide for the state and regional advisory committees, the implementation of a system to categorize the various trauma care facilities, the development of a centralized registry to collect data on trauma care for quality improvement purposes, and rulemaking authority.

In a retrospective analysis, the Critical Illness and Trauma Foundation of Montana reviewed all traumatic deaths in the state occurring from October 1, 1990 to September 30, 1992. The study revealed an overall preventable trauma death rate of 13%. A subsequent study in 1998 was conducted after the state's trauma system

implementation. The overall preventable death rate had decreased to 8%. The study's conclusion proves that efforts to initiate a voluntary state trauma system have had a positive effect on the preventable death rate. However, rates of preventable death have not yet reached what would be ideally seen in a well-established trauma system.

As required by 50-6-402, MCA, the department is proposing these administrative rules to further the goals of Montana's trauma care system.

RULE I DEFINITIONS

Appendix I of the "2006-2010 Montana Trauma System Plan" contains detailed criteria for the four levels of trauma facility designation as defined in Rule V. Because the criteria in Appendix I are extensive, very detailed, and consist of 28 pages of material, the department decided that it would reference the appendix throughout the rules for easier comprehension and implementation. The department therefore proposes to incorporate the appendix by reference.

The criteria in Appendix I are necessary to provide for consistency in the facility designation process listed in Rule V. The criteria are based on Chapter 23, Trauma Facilities Criteria, of the "ACS Resources for Optimal Care of the Injured Patient: 1999", which were adopted by the STCC and included in the initial Montana trauma system plan published in 1994. These criteria have been reviewed and revised with input from the STCC and the three RTACs to be consistent with the updated 1999 ACS document. Trauma facility consultation visits have been conducted for most of the potential trauma facilities in the state, and input received during these visits also confirmed that the criteria devised in Appendix I was appropriate for Montana. The STCC approved the final version of Appendix I in their meeting held on February 14, 2005.

Appendix J of the "2006-2010 Montana Trauma Plan" pertains to the statewide trauma registry. It includes provisions for confidentiality, data collection methods, computer data submission procedures, paper data forms, patient inclusion criteria, and a dictionary of registry terms. Appendix J supplements the requirements for a statewide registry found in proposed Rule XIV.

Last updated in November 2005, the department developed the criteria in Appendix J with the input and consensus of a multi-disciplinary group of medical professionals representing various sizes of health care facilities. The criteria are based on professional experiences, expert recommendations, and results from evidence-based research. The criteria include data on patients who had the potential to sustain serious or life-threatening injuries, and how they would benefit the most from a facility's trauma care program, the regional trauma system, and the state trauma system. The defined data elements were selected to support a facility's and trauma system's performance improvement efforts.

Furthermore, Appendix J was developed to meet the needs of both small and large

health care facilities that have varying levels of resources. It provides for electronic and paper data collection formats. Appendix J also provides the quarterly electronic schedule to transfer data to the centralized trauma system registry.

Appendix J's criteria are extensive, very detailed, and consist of over 60 pages of material. The department decided that it would reference the appendix throughout the rules for easier comprehension and implementation. For this reason, the department proposes to have Appendix J incorporated by reference.

Other definitions in Rule I are needed to explain the commonly-used terms in the ensuing rules. All are related to the composition and duties of the regional trauma systems, regional advisory committees, and the state trauma care committee as found in Rules II through IV; the application, review, approval, and status of the state's designation system for the various levels of trauma facilities, seen in Rules V through XIII; and the terminology used for describing the requirements needed for the statewide trauma registry as provided in Rule XIV.

RULE II TRAUMA REGIONS

50-6-402(2)(b), MCA, requires the department to adopt rules to designate trauma regions throughout Montana, taking into consideration geographic distance from available trauma care, transportation modalities available, population location and density, health care facility resources, historical patterns of patient referral, and other considerations relevant to the optimum provision of emergency medical care.

The three regions specified in Rule II are those that currently exist. Rule II is needed to codify the regional delineations. The regions are designed to provide a supporting system for the physicians' care of the trauma patient. The regional trauma centers in each of the regions have successfully obtained verification from ACS as level II trauma centers. Each regional center provides a tertiary referral center for trauma patient referral within each region.

A regionalized approach, reflecting existing patient transfer patterns, assures adequate trauma care coverage. This system is consistent with the trend to regionalize all health care, which is based on the premise that quality and cost effectiveness will improve with experience and patient volume in smaller geographic regions.

Due to the inherent differences in population density, geography, and trauma care resources, it is recognized that the design of each trauma region must be somewhat individualized to achieve the objective of optimal patient care. The differences between communities require flexibility to develop the most appropriate system to fit the individual trauma region.

The alternative to the regional approach specified in Rule II is to not have such a system. The department rejected that alternative because 50-6-402(2)(b), MCA, requires a rule designating trauma regions. Besides the statutory requirement, the

trauma regions have been functionally existing for over a decade and are supported by the health care providers in this state. The regionalized approach has proven to be beneficial for a quality trauma care system in this large and mostly rural state.

RULE III REGIONAL TRAUMA CARE ADVISORY COMMITTEES

50-6-402(2)(a)(iii) and (viii), MCA provide that the department shall adopt rules to establish operational procedures and criteria for the Regional Trauma Advisory Committees (RTACs) as well as rules concerning the committees' duties, responsibilities, and functions.

The RTACs give each regional system a voice in the development and implementation of an integrated regional trauma system. They serve to coordinate the regional system of care among the trauma facilities in the region so that efficient and prompt interfacility communication and transfer can take place according to patient need. The RTACs assist in developing local solutions to improve and maintain consistency in trauma care. They further provide case reports and trauma registry data so that the STCC and the department can coordinate better statewide trauma care between the regions.

Rule III(2) provides for the subcommittee structure of each RTAC. These subcommittees support regional education, emergency medical service issues, performance improvement, and injury prevention activities. Subcommittee focus on those issues has proven to be beneficial for providing quality trauma care in each region and for the state as a whole.

Rule III is needed to codify the regional committee delineations and their functions. The rule provides legitimacy to the RTACs. An alternative to the RTACs is to not provide a forum for facility participation in their regional trauma systems. Since the trauma regions have been functionally existent for over a decade and are supported by the health care providers in the state, the department rejected this alternative. Another alternative considered was to have only one advisory committee. That alternative was rejected because the large distances in the state would limit facility participation.

RULE IV STATE TRAUMA CARE COMMITTEE

Like that for RTACs, 50-6-402(2)(a)(viii), MCA, requires the department to adopt rules to establish the duties, responsibilities, and functions of the state trauma care committee (STCC) created by 2-15-2216, MCA.

As mentioned earlier, the multi-disciplinary trauma system task force which met from 1990 to 1994 has evolved into the present day STCC. This group of health professionals has been meeting on a quarterly basis for over a decade. It has been involved with the Montana trauma system development since its inception and has provided hundreds of hours of voluntary participation in the implementation and evaluation of the system.

Participants in the STCC include two members from each RTAC, the department's trauma coordinators, a nurse or physician representing the Indian Health Service, and representatives of the Montana Hospital Association, Montana Medical Association, Montana Emergency Nurses Association, Montana Private Ambulance Operators, and the Montana chapter of American College of Emergency Physicians. The involvement of leaders from Montana's numerous sovereign Indian nations is critical for improving and maintaining a comprehensive trauma system in Montana. Although Montana law does not bind these nations, the department recognizes them as part of the comprehensive care system.

The STCC also assists in the development and implementation of a statewide trauma registry database and performance improvement system, assuring compliance with appropriate state laws, regulations and local policies, procedures, and contractual arrangements. The STCC uses the data from the registry to analyze the impact and results of the system, and to formulate appropriate changes to assure the highest possible level of patient care. The STCC also oversees the RTACs in their performance improvement, system evaluation, education and training programs, and injury prevention efforts.

Guidelines from the ACS support the intent behind Rule IV. The ACS recommends that people who are most closely involved in trauma care should lead in the development of a trauma care system. The ACS suggests that a trauma system will only succeed if all involved parties participate in the system's planning, development, and implementation.

Rule IV is needed for the coordination and adoption of criteria for optimal trauma care in Montana. The STCC provides a vehicle for health care providers to develop guidelines and conduct ongoing assessments of the state's trauma needs and resources. The alternative considered was to not have a rule establishing the duties, responsibilities, and functions of the STCC. The department determined that not having a rule outlining the duties and makeup of the STCC would cripple the department's continuous efforts to build an effective trauma system. The STCC has a history of providing critical oversight of the state's delivery of trauma care.

RULE V LEVELS OF TRAUMA FACILITIES

50-6-402(2)(a)(i), MCA, provides that the department shall adopt rules that establish various levels of trauma facilities. When enacting this statute, the 1995 state legislature wrote in its statement of intent that the department was to adopt rules to "(5) establish four levels of trauma care facilities, each having a different capacity for trauma treatment: (a) regional centers capable of providing advanced trauma care to a region; (b) area trauma hospitals capable of handling most trauma patients within their ordinary service areas; (c) community trauma hospitals with limited emergency and surgical coverage; and (d) trauma receiving facilities, such as hospitals with no surgical coverage and medical assistance facilities." 1995 Laws of Montana, Chapter 579.

In Rule V, the department has listed four levels of trauma care facilities that mimic the legislature's statement of intent. The levels include (a) regional trauma centers; (b) area trauma hospitals; (c) community trauma facilities; and (d) trauma receiving facilities.

The trauma care system is the network of definitive care facilities that provide a spectrum of care for all injured patients. The classification scheme listed in Rule V is not a ranking of medical care, but is a ranking of resource availability. To avoid the concept that one level is necessarily better than another, numeric indicators for facility designation have been avoided. Rather, the rule provides descriptive titles of the trauma care capabilities of the various facilities.

The department devised the state's levels of facility resources in Rule V based on national criteria and with the assistance of health professionals on the STCC and RTACs. The criteria were developed to provide guidance to facilities in organizing their trauma response at the level of participation they choose. The requirements for each level are contained in Appendix I of the "2006-2010 Montana Trauma System Plan".

The designation of definitive trauma care facilities is essential to the development of a trauma care system so that the needs of all injured patients are addressed. Few individual facilities can provide all resources to all trauma patients in all situations. A designation system emphasizes the need for various levels of trauma centers to cooperate in the care of the injured patient so precious medical resources are not wasted.

The alternative considered to Rule V is having no determination of the levels of trauma facilities by the department. This option was not chosen because the department believes that having a level system assures that various health care facilities have the required resources to provide effective emergency care to critically injured patients. The level system also allows quick patient transfers to facilities that have level designations indicating more resource availability to assist the patients. Having required resources is the key to an effective trauma care system.

Another reason for not selecting any alternative to Rule V is that the Universal Billing 92 (UB-92) codes, which are the national de facto health institutional billing claim standard, have similar categories as Rule V for trauma facility care. Universal Billing codes are developed and overseen for maintenance of integrity by the National Uniform Billing Committee, comprised of the members of the American Hospital Association and all major payers, including the federal Centers for Medicaid and Medicare (CMM).

In order to use the appropriate trauma care UB-92 codes for Medicaid and Medicare billing, CMM requires the trauma facilities to be designated by a state or local governmental authority or verified by ACS. Because Montana currently has no identified levels of trauma centers, most facilities have been denied the opportunity

to bill for trauma care by using the applicable UB-92 codes. Rule V allows the department to designate trauma centers, thereby allowing the state's facilities to receive federal reimbursement for trauma team activation.

RULE VI COMPOSITION OF SITE REVIEW TEAMS

Pursuant to 50-6-402(2)(a)(i), MCA, the department is to adopt rules that establish site survey procedures.

In order to designate the level of a trauma care facility, the facility's capability and performance must be reviewed. This assessment is best accomplished by an on-site review of the facility by a team of health care providers who have experience in providing trauma care. Having on-site reviews is consistent with the practices of the ACS and other state trauma systems, therefore the department determined that such a system would be beneficial when assessing levels of trauma care facilities in Montana.

The ideal site review team, identified as meeting the experience requirements specified in Rule VI, are the trauma medical director and a registered nurse employed in the role of the trauma coordinator. These two positions, widely recognized as the leaders of a facility trauma program, have been determined as being best able to accomplish the considerable responsibilities outlined in these rules. For those facilities with surgical capabilities, the commitment of surgeons to the improvement of trauma care is mandatory, therefore the trauma medical director on the team must be a general surgeon with the required trauma expertise. The department has found that the majority of other states with successful designation systems have the same staffing on their site review teams.

The department rejected not having Rule VI because 50-6-402(2)(a)(i), MCA requires such a rule. Also considered was not identifying the composition of the site review team. Doing so would leave the review process open to inconsistencies. Also, the lack of qualified team members may result in deficient or fatal care for trauma patients being treated at facilities with wrong designation levels. The department found this option to be unsatisfactory.

RULE VII DESIGNATION PROCEDURES FOR FACILITIES NOT VERIFIED BY AMERICAN COLLEGE OF SURGEONS

50-6-402(2)(a)(i), MCA, provides that the department must adopt rules that establish various levels of trauma facilities.

Rule VII outlines the application requirements and site review procedure for health care facilities wanting a state designation of their trauma care program, as specified in Rule V. The site review process is proposed to consist of an expert trauma review team visiting all areas of the facility that provide trauma care. The process is designed to be constructive in assisting the facility's goal of providing optimal care. The site review team is responsible for evaluating medical records of trauma

patients, and correlating patient care with the performance improvement program. At the end of the on-site review, the site review team is to summarize its findings to the facility in an exit interview.

The team is then responsible for writing a confidential performance improvement report to be provided to the facility for the purposes of performance improvement and peer review. This report is not used to determine state designation or ACS verification.

The site review team is also responsible for completing a nonconfidential trauma facility designation report that provides an evaluation of the facility. The report specifies how the facility complies with the trauma facility resource criteria contained in Appendix I of the Montana trauma system plan. The report also recommends a facility designation to the STCC designation subcommittee and the department. The department has the option of fully designating a facility, providing provisional designation, or denying designation based on the site review team's report.

The process outlined in Rule VII is consistent with that used by other state trauma systems for facility designation and by the ACS for its trauma facility verification. The alternative considered for Rule VII was to not provide for a state designation process and instead adopt the ACS trauma facility verification as the state's sole designation process. The department found that this option was not viable because: (1) the majority of healthcare facilities in Montana that are identified as potential trauma facilities would not meet the lowest level of the ACS trauma facility verification, thus excluding those facilities found to be vital to the state's rural trauma system design; and (2) the costs for facilities to participate in the ACS consultation and verification program would be significant for them. Providing the state trauma facility consultation and designation program that is consistent with the practices of the ACS at no cost to the facility ensures facility participation in the state trauma plan.

RULE VIII DESIGNATION PROCEDURES FOR FACILITIES VERIFIED AS TRAUMA FACILITIES BY AMERICAN COLLEGE OF SURGEONS

50-6-402(2)(a)(i), MCA, states that the department shall adopt rules that establish various levels of trauma facilities.

Rule VIII provides health care facilities with the option of receiving ACS verification. The ACS classifies trauma centers based on resource availability, and defines and redefines those activities necessary to maintain excellence in trauma care. The ACS standards and procedures have been used as a guide for the trauma care system development in Montana and throughout the U.S.

Currently there are six hospitals with ACS trauma center verification, and two are scheduled for consultation visits from the ACS. All of these facilities, which are located in each of the state's trauma regions, have voluntarily gone through the rigorous ACS process. The distinction of having ACS trauma center verification

denotes a significant medical and administrative commitment to provide excellence in trauma care leadership in the region. Each of these lead facilities is bearing the financial costs associated with ACS verification.

In areas where there are non-ACS designation authorities such as that operated by a state, the ACS will not perform its verification review without the designation authority's approval. Rule VIII will facilitate the coordination of efforts for ACS verification and the state designation process. The facility will complete the prereview questionnaire required by the ACS and provide a copy for the department and the STCC designation subcommittee to review. The department will participate with ACS's team during site reviews of facilities.

The confidential report generated by the site review team will be provided only to the facility for performance improvement and peer review purposes. The department will only require a copy of the letter from the ACS indicating if the facility has achieved successful ACS verification and the time duration for the designation. Copies of the letter will be made for the STCC designation subcommittee for its use.

The coordination of state and ACS activities for facility verification has already been implemented in Montana. The department and the STCC have approved the plan. This coordinated approach has allowed the department to attend six of the seven recent ACS visits in Montana. All parties involved in this process to date have favorably received it.

The alternative to developing Rule VIII was to not develop a coordinated approach to recognize and implement the ACS consultation and verification process in the state designation program. The department has already seen successful voluntary hospital participation in the ACS process. Not allowing for the ACS designation would result in those facilities with ACS verification to spend additional money and time to comply with the state system. Doing so would contribute to dissatisfaction and decreasing facility participation in the state trauma system. The department adheres to the principle that an organized team approach in providing care for the injured patient will result in an effective trauma system. The department determined that not having Rule VIII would be contrary to its cooperative approach.

RULE IX LENGTH OF DESIGNATION

Under 50-6-402(2)(a)(ii), MCA, the department is to adopt rules that establish procedures for the time duration of the various designated levels of trauma facilities.

The three-year term for full designation of Montana trauma facilities is the same as that for ACS-verified facilities. Having the same duration terms helps coordinate the efforts needed for the effective and efficient implementation of Rule VIII.

Furthermore, the three-year time period is the same length as other states that require their own classifications of trauma facilities. The term has been proven by other states' programs to not be unduly burdensome to health care facilities having

to endure reviews every three years. Also, the length of time allows frequent opportunities to assist the facilities in the evaluation and improvement of their trauma care.

An alternative considered was to allow for a four-year term for facilities that are fully designated by the department. The Department rejected that option because it would not allow for more frequent checks on the facilities to assure that they are capable of providing the required trauma care. Also, a different term length than that for ACS verification may lead to confusion among health care facilities.

Rule IX(2) provides a six-month interim period for facilities whose ACS verification expired and they are in the process of being reverified. ACS does not provide for an interim period. The department is providing the six-month term for state designation because the six-month time period provides a reasonable time for that facility to continue its state-designated status while an ACS reverification visit is being actively sought and scheduled, so as to allow for state participation in the site review process.

Rule IX(3) allows the department to grant a one-year term for provisional designations. Such designations are given to those facilities that have deficiencies in meeting the required designation but are substantially compliant with the resource criteria. The department chose the one-year term because it was found to provide sufficient time for provisional facilities to correct their deficiencies. The department rejected the idea of having a two-year term because the longer period would not in facilitate the prompt correction of any found deficiencies.

ACS does not provide a provisional level of verification. Because the state designation is a voluntary process, the department has opted to include provisional designation status as an additional incentive for facilities to participate and to further encourage active development of optimum trauma patient care processes.

RULE X TRAUMA FACILITY REQUIREMENTS

Pursuant to 50-6-402(2)(a)(i), MCA, the department is to adopt rules that establish the various levels of trauma facilities and the standards each facility is required to meet concerning personnel, equipment, resources, data collection, and organizational capabilities.

Rule X provides options for health care facilities that have lost the critical resources necessary to provide optimal trauma patient care at a designated level. If a designated trauma facility does not have the resources needed to meet their level of designation, Rule X requires the facility to inform the department in a timely manner so the department can make necessary adjustments in the state trauma system coordination.
Rule X(2) allows for the continued level designation of a health facility that is temporarily out of compliance with the requirements needed for the designation level. If the required resources are not available for less than a week, the facility can

elect to develop and follow a plan to divert trauma patients to the closest trauma facility known to have the necessary resources. It is acknowledged that this option can be employed only when there is another facility within a reasonable distance for which to divert seriously injured patients. If a facility will not have the required resources for over a week, the department is to be notified promptly in order to develop a contingency plan to compensate for the lack of required resources, as further described in Rule XI(7).

The Montana trauma system has been designed from the outset to be a voluntary program. Facilities may voluntarily elect to become a trauma facility in the state. As such, Rule X(3) provides for a facility to voluntarily terminate its trauma designation. The requirement that the facility provide a 90-day written notice to the department of its intent to terminate its trauma designation allows the department, the STCC, and the RTAC to develop a plan for how to deal with the loss of that trauma facility in the best manner possible.

If a facility that voluntarily terminates its trauma designation wishes to be reinstated as a trauma center, Rule X(4) requires them to go through the trauma designation process again as outlined in Rule VII or Rule VIII. Reapplying for the designation is necessary to assure the facility meets the criteria necessary to function at the level of trauma designation it seeks.

The alternatives considered for Rule X included allowing a two-week period for a designated facility to lack the required resources needed for the facility's designation level. That option was rejected because it was felt that this was too long without a contingency plan being developed to assure the community is being adequately covered for its trauma care. Another alternative considered was to require the facility to provide the department with a 60-day notice for terminating their designation status. That time period was also rejected as it was determined that this would not provide sufficient time for the STCC and RTAC to develop a plan to deal with the loss of the trauma facility.

RULE XI COMPLAINT INVESTIGATION, REVOCATION, OR EMERGENCY SUSPENSION

50-6-402(2)(a)(ii), MCA, requires the department to adopt rules to establish and coordinate the statewide trauma care system, including rules on the procedures for revocation of a trauma facility’s designation, complaint investigation, and emergency suspension of the designation.

Rule XI provides the department with authority to investigate complaints and take appropriate actions in order to assure that optimal patient care is delivered within the state trauma care system. The rule allows the department to be responsive to any events that may hinder the state trauma system’s mission of preventing death or disability to injured patients.

Rule XI(3) allows the department to access the health care facility's documentation

during any investigation. Trauma patient medical records are needed for specific patient follow-up, and they provide the best information to evaluate trauma patient care. Inpatient and emergency department logs help to identify seriously injured patients cared for at the facility. Trauma performance improvement documentation helps to assure that the facility has identified opportunities for performance improvement, developed an action plan to correct any deficiencies noted, and monitored the implementation of the corrective actions. This practice of reviewing the health care facility documentation listed above has been found to be successful for other designating authorities in the U.S.

Rule XI(4) provides the list of actions the department may take after investigation. The department's course of action will depend on the severity of the violations found from the investigation.

Rule XI(4)(c) allows the department to require the facility to submit a corrective action plan to eliminate any potential for the suspension or revocation of a designation level. Often the best opportunities for improvement come from a performance evaluation, learning from mistakes, and making necessary changes. There is no evidence that overly punitive measures are effective for less major violations, therefore the department allows itself the option of requiring corrective action plans.

Rule XI(5) and (6) provide for the emergency suspension and revocation of a facility’s trauma designation after department investigation. The department is to initiate the emergency suspension if a violation of these rules creates a substantial threat to public health or the designated facility ceases to be a health care facility. Emergency suspension is needed to prevent death or disabilities to trauma patients due to a facility not possessing and/or providing the proper health care resources. The option for the department to revoke a facility’s designation, seen in Rule XI(6), is necessary for the department to take the most appropriate action for the most egregious of violations. The facility has the right to contest the department's emergency suspension or revocation in a fair hearing, as described in Rule XII.

Rule XI(7) allows the department to take certain actions in cases when a facility will be temporarily out of compliance with its designation criteria for more than one week. The options allow for leniency by allowing the facility to submit a plan of correction, depending on the severity of the criteria violation. If a facility's noncompliance creates a substantial risk to the public’s health, the department may suspend the care designation on an emergency basis.

The alternatives considered for Rule XI included allowing the department wider access to review the facility during investigations. The department determined that the requested documentation specified in this rule should, in most circumstances, provide sufficient access to the facility to verify compliance. The department's review process and the ability to make decisions about the facility's quality of trauma care are necessary to effectively verify compliance with the remainder of these rules.

Also, the graduated adverse actions that the department may take match those for license violations in other areas that the department regulates. For all state license actions, 2-4-631(3), MCA, requires all state agencies to provide notice to the license holder before taking any action against a license except when the agency finds that "public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order".

RULE XII DENIAL, MODIFICATION, SUSPENSION, OR REVOCATION OF DESIGNATIONS, AND APPEAL

Under 50-6-402(2)(c), MCA, the department shall adopt rules that establish the procedure to be followed by a health care facility to appeal a decision by the department that affects the facility's designation as a trauma facility. The procedure compliments 50-6-410(5), MCA, which allows the department to deny or revoke a health care facility's designation as a trauma facility upon written notice to the health care facility, allows the facility to appeal the decision within 30 days after it receives the department's written notice, and requires the administrative appeal to be conducted through an informal process provided in 2-4-604, MCA.

In Rule XII, the department requires that its written notice of the denial or revocation is to be sent to the health care facility via certified or registered mail. The rule further provides that the informal appeal process provided for in 2-4-604, MCA, be conducted in accordance with ARM 37.5.117 and 37.5.311. ARM 37.5.117(1)(h) provides that hearings for the "designation of health care facilities as trauma facilities under Title 50, chapter 6, part 4, MCA" are to be conducted in accordance with the various administrative hearing procedures in ARM Title 37, chapter 5, subchapter 3. ARM 37.5.311 provides the general procedure for conducting an informal reconsideration of the department's actions.

In order to be fair and reasonable, health care facilities that are designated by the state as trauma facilities must have an avenue to challenge the department's decisions if those actions are perceived as unreasonable. Rule XII provides such a process. Because the department has set procedures for all of its administrative appeals found in ARM Title 37, chapter 5, the department did not consider any alternatives. The department chose the procedures in Rule XII so that the appeals process for the denial or revocation of trauma care designation would be consistent with all other appeal actions within the department.

RULE XIII REAPPLICATION FOR DESIGNATION

Rule XIII(1) allows a health care facility to reapply for designation after the department has denied the designation. The facility must enact changes in their processes in order to receive designation. The six month period prior to reapplication provides an appropriate and reasonable period for the facility to make the appropriate changes. The time period is also adequate for the facility to establish a track record of its enacted changes, and provides an evaluation of the effectiveness of those enacted changes.

The department rejected the alternatives of a shorter or longer time period than six months because a lesser time period would not provide for an adequate track record time period to verify the effectiveness of the facility's designation efforts, and a longer time period would unduly limit the facility's access to reapplication.

Rule XIII(2) provides for a facility whose designation was revoked to petition the department for redesignation after one year from the time the original designation was revoked. For the department to revoke a facility's designation, that facility would have met criteria in Rule XI(6)(a) through (e). Usual practice across the nation provides for a one-year term for a facility to enact significant changes to correct any deficiency and show an adequate track record proving that the corrections will remain in place.

The Department rejected the alternatives of a shorter or longer time period than one year because revocation of a designation is based on the significant lack of compliance and a lesser time period does not provide for an adequate track record time period to verify effectiveness of significant changes enacted. A period longer than one year would not facilitate the timely correction of such noncompliance.

RULE XIV TRAUMA REGISTRIES AND DATA REPORTING

A "state trauma register" is defined in 50-6-401(6), MCA, as trauma data relating to a specific patient or health care facility that is maintained by the department in an electronic format and that has the primary purpose of facilitating peer review and quality improvement for a health care facility or a trauma care system.

50-6-402(1), MCA, requires the department to develop and adopt a statewide trauma register. 50-6-402(2)(a)(vi), MCA, directs the department to adopt rules establishing requirements for the collection and release of trauma register data. 50-6-402(2)(d), MCA, requires the department to specify the information that must be submitted in order to provide statistical evaluations of the state and regional trauma care systems, plan prevention programs, assess trauma-related educational priorities, and determine how trauma facilities and emergency medical services comply with the department's protocols and standards. 50-6-402(2)(e), MCA, requires the department to establish an electronic format and develop requirements for health care facilities in order to qualify as a hospital trauma register.

Having a statewide trauma register is a critical component of a trauma care system. Decision making for optimal care of the trauma patient should be based on understanding the causes, treatment, and outcomes associated with the injury. A trauma registry provides for the collection, storage, and reporting of information about trauma patients so that optimal care can be delivered to future trauma patients. The ACS acknowledges the importance of having data from trauma registries, therefore it requires facilities to have registries in order to qualify for ACS verification.

The data in the trauma registry can be used in a variety of ways, as follows:

For performance improvement, the cumulative data in the registry facilitates the objective review of the care provided and identifies variations in the process or outcome of care. The regional and statewide trauma systems can monitor a variety of parameters to compare benchmarks across systems of care, track variability and outcomes, identify opportunities for improvement, and measure progress.

For public health, trauma registry data provide information regarding incidence, care, cost, and outcome of injuries in a specific region and across the state. This information may be used to inform public officials about trauma as a public health problem, thus serving as a basis for legislation and regulatory efforts to benefit injury prevention programs.

For outcome research, the registry database facilitates the evaluation of strategies to improve the care of the injured patient.

For resource utilization, the trauma registry data support the determination of resources required by the individual facilities' trauma program and by the department for trauma designation.

In 1989, the department, with input from the trauma task force, selected a trauma registry software product to be provided at no charge to participating health care facilities. All training costs for those individuals participating with the trauma registry at the facilities have been assumed by the department, including costs for travel if required.

After a period of use, significant problems were identified with the trauma registry software which resulted in the department purchasing new registry software in 2002. Twelve facilities have been provided with the software and the associated performance improvement module to assist in the facilities' performance improvement efforts.

Through a combination of federal grants and money allocated from the state general fund, the department has paid the costs for the software, user requested modifications, technical support and updates, training, and attendance at national conferences and the annual STCC meeting. The health care facilities using the registry bear the costs of supplying sufficient memory space on the hard drive of a computer to run the software application in a location that protects confidential patient information. The facilities are also responsible for their costs of having their personnel abstract the information from medical records and enter the data in the trauma registry. The total cost is impossible to estimate, but the cost for personnel time can be calculated at approximately one hour per patient medical record.

Depending on the number of trauma patients they serve, health care facilities may use the computerized version of the registry or provide written information on

registry forms developed by the department. Rule XIV requires the use of the computerized registry for regional trauma centers capable of providing advanced trauma care to a region, and community trauma hospitals that have limited emergency and surgical coverage. These types of facilities serve high volumes of trauma patients. These facilities are also the ones who have requested the registry software and most have been using it for many years.

The department developed paper data abstraction forms with RTAC input for use by health care facilities serving smaller volumes of trauma patients. Such facilities include area trauma hospitals that are capable of handling most trauma patients within their normal service areas, and trauma receiving facilities such as hospitals with no surgical coverage. The department pays for the forms used and mailing costs and provides the computer and personnel to enter the information into the central site trauma registry.

The department is considering a web-based version of the registry so that the collected data can be in a central site. The department assumes the costs of the performance improvement review performed by the state trauma coordinator with the written feedback given to the facility and any training costs for personnel and attendance at the statewide trauma meeting. The department will also assume any costs that may occur in processing trauma registry reports requested by the participating facilities.

Rule XIV(4) lists the data that health care facilities must collect and report for the statewide registry. This information is the same specified in Appendix J of the "2006-2010 Montana Trauma System Plan". The rationale for the use of Appendix J and information on how it was developed is listed under Rule I, Definitions.

The medical data collected for the trauma registry are covered by all medical record privacy law. 50-6-415(1), MCA, provides that the health care facility’s data may only be given to the facility's peer review committee, the RTAC of the region in which the facility is located, the STCC, and the Department. The data are also subject to the federal Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule), found in 45 CFR section 164.501, et seq. Pursuant to 45 CFR section 164.512(b)(I) of the Privacy Rule, covered entities such as health care facilities, the Department, and the STCC and RTACs are "authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions".

Rule XIV is necessary to reduce the number of deaths and disabilities caused by trauma. Optimal trauma care requires each trauma patient to get to the right facility with the appropriate care resources within the right time period. In order to accomplish this goal, medical personnel who are first responders, emergency rooms, and inpatient hospital trauma services must identify factors that keep patients

from reaching the most appropriate facility in a timely manner and then must work together to systematically eliminate or reduce those factors. Analysis of these data will provide a way to assess the effectiveness of the current responses to trauma patients and to then target the trauma system quality improvement efforts.

The department did not consider any alternatives when devising Rule XIV. 50-6-402, MCA, requires the department to develop rules and implement a statewide registry. Furthermore, Montana has been using a trauma registry system since 1989. A trauma registry provides the data that is essential to understand, modify, are and improve this state's trauma system. The data may indicate needed changes in local, regional, or state trauma care patterns, protocols, and prevention techniques.

4. Interested persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena, MT 59620-2951, no later than 5:00 p.m. on April 20, 2006. Data, views, or arguments may also be submitted by facsimile (406)444-1970 or by electronic mail via the Internet to dphhslegal@mt.gov. The department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.

5. The Office of Legal Affairs, Department of Public Health and Human Services has been designated to preside over and conduct the hearing.

/s/ Dawn Sliva
Rule Reviewer

/s/ Joan Miles
Director, Public Health and Human Services

Certified to the Secretary of State March 13, 2006.